UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-CV-12257-PBS** **Subcategory Case. No. 06-11337**
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS	**Hon. Patti B. Saris**

DEY DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION *IN LIMINE* TO EXCLUDE FROM EVIDENCE THE REPORTS AND TESTIMONY OF STEPHEN W. SCHONDELMEYER

Defendants Dey Pharma, L.P. (formerly known as Dey, L.P.), Dey, Inc., and Dey L.P., Inc. (collectively "Dey") submit this memorandum of law in support of their Motion to Exclude From Evidence the Reports and Testimony of Stephen W. Schondelmeyer, Pharm. D., Ph.D.

PRELIMINARY STATEMENT

Dr. Schondelmeyer, a professor at the University of Minnesota, has been retained by Relator, Ven-a-Care of the Florida Keys, Inc. ("VAC"), to give expert testimony and/or provide assistance with numerous drug pricing litigations around the country. He is essentially VAC's in-house expert — he was first hired by VAC in Texas's action against Dey, Inc. in 2002 and now travels from state to state offering essentially the same opinions and conclusions against different manufacturers. Dey requests that the Court exclude the following opinions proffered by Dr. Schondelmeyer:

i. All testimony opining that federal and state law required Dey to report drug prices which were "generally and currently" paid by providers.

ii. All testimony purporting to state what Dey knew or intended.

iii. All testimony purporting to state what Medicare, Medicaid or the 50 state Medicaid programs knew or intended and whether Dey's reported prices caused Medicare or Medicaid to overpay.

As to item (i), Dr. Schondelmeyer usurps the role of the Court and engages in improper legal analysis by offering nothing more than his interpretation of federal and state law, based on a selective reading of two federal regulations. He does not rely on any research, scholarly writings, or other sources of support traditionally relied upon by experts. Moreover, Dr. Schondelmeyer's interpretation of the law is incorrect. The government has never told any manufacturer that it must report the prices "generally and currently paid" — as Dr. Schondelmeyer opines it should have. Finally, in rendering his legal opinion, Dr. Schondelmeyer ignores legal authority which contradicts his opinion and relies on regulations which do not apply to manufacturers like Dey.

Dr. Schondelmeyer's opinion concerning the knowledge and intent of Dey should also be excluded (item (ii)). It is not proper to offer him as an expert in mind reading. Cloaking factual evidence regarding knowledge and intent as the testimony of an "expert" is highly prejudicial and does nothing to assist the jury. In fact, Dr. Schondelmeyer concedes that a jury is fully capable of reading and interpreting the documentary evidence of Dey's knowledge and intent. Further, Dr. Schondelmeyer's opinion of Dey's knowledge and intent is based on a woefully inadequate review of the record, namely some twenty-five documents cherry-picked for him by VAC's counsel from a database of literally hundreds of thousands or pages of documents.

Nor does the Court need Dr. Schondelmeyer to tell the jury what Medicare or Medicaid "knew" and "intended" based on his selective review of documents or testimony (item (iii)). To the extent the government intends to put on evidence of what it knew or intended, it should do so with fact witnesses who have personal knowledge and can be cross-examined. Dr. Schondelmeyer's opinion that Defendants reported "inflated" prices causing Medicare and

Medicaid to overpay is not based on any scholarly research or examination of any claims. Dr. Schondelmeyer did not conduct any systematic or scientific study of the prices for Defendants' products. He appears only to have looked at a few documents for a fraction of the hundreds of drugs at issue at what appears to be random points in time. His opinion is nothing more than subjective belief and unsupported speculation based on his review of a handful of documents selected by counsel.

ARGUMENT

As the "gatekeeper" charged with ensuring the reliability and relevance of all expert testimony, *see Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993) and *Irvine, IRG v. Murad Skin Research Labs.*, 194 F.3d 313, 320 (1st Cir. 1999), this Court should exclude the opinions of Dr. Schondelmeyer for the following reasons:

i. Dr. Schondelmeyer is not qualified to offer a legal opinion on what drug prices federal and state law requires manufacturers to report. In interpreting federal regulations (incorrectly), he usurps the role of the Court.

ii. Expert testimony on a party's intent or knowledge is improper because it usurps the role of the jury. Dr. Schondelmeyer's opinions regarding what Dey knew or intended are based on a selective and wholly inadequate review of the record and so lack a reliable foundation and are misleading.

iii. Dr. Schondelmeyer's opinions regarding the knowledge and intent of Medicare and Medicaid is similarly based on a narrow review of the record and improper weighing of the evidence. Dr. Schondelmeyer is also not an economist and has done no study to determine whether providers were "overpaid" by Medicaid and Medicare, or whether Dey caused any such "overpayment."

I. DR. SCHONDELMEYER'S TESTIMONY PROFFERING LEGAL OPINIONS REGARDING STATUTES AND REGULATIONS SHOULD BE EXCLUDED

A. Dr. Schondelmeyer Improperly Opines Regarding The Law

Dr. Schondelmeyer concedes that he is not a lawyer and lacks expertise to interpret

statutes, laws and regulations for the jury "in a legal sense." (Tr. at 200:22-201:4.)[1] Yet, his report offers little else. Specifically, Dr. Schondelmeyer repeatedly opines that Medicaid and Medicare require manufacturers, like Dey, to report drug prices that are "generally and currently paid by providers," and not list or undiscounted prices. His report makes clear that this legal conclusion is based solely on his (incorrect) interpretation of a single Medicaid regulation and a 1977 Medicaid directive:

- "The Medicaid program chose to base prescription payments on 'estimated acquisition cost.' The intent and definition of estimated acquisition cost dates as far back as 1977 as described in an HHS document titled, 'Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC).' This HHS memo to state Medicaid directors stated 'The intention of the final Medicaid regulations on drug reimbursement is to have each state's estimated acquisition cost as close as feasible to the price generally and currently paid by the provider. The states are, therefore, expected to set their ingredient cost levels as close as possible to actual acquisition cost.'" (Rep. at ¶ 53.)[2]

- "The term 'estimated acquisition cost' (EAC) was further defined as 'the price generally and currently paid by providers for a particular drug in the package size most frequently purchased by providers.'" (Rep. at ¶ 54.)

- "Medicaid and Medicare currently and historically have relied upon manufacturers' reporting of prices that do reflect the 'prices generally and currently paid by providers' in the marketplace." (Rep. at ¶ 80.)

- "Dey's premise that states 'favored using' inflated AWPs for policy reasons 'is not consistent with, and is in direct opposition to, long standing Medicaid statutes, regulations, policies, and practices.'" (Rep. at ¶ 158.)

These conclusions are based, not on any scholarly study or expertise, but rather on his interpretation of regulations issued by the Department of Health and Human Services, such as HHS action transmittal, HCFA-AT-77-113 (MMB), dated December 13, 1977, and the 1987

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1 References to "Tr." are to the depositions of Dr. Schondelmeyer, dated February 25, 26, 27, May 21, and 22, 2009, attached as Exhibit A to the Declaration of Neil Merkl.

2 References to "Rep." are to the Expert Report of Dr. Schondelmeyer, dated January 22, 2009, attached as Exhibit B to the Declaration of Neil Merkl.

federal regulations embodied in 42 C.F.R. 447.301. (Rep. at ¶¶ 52, 53.) Indeed, the phrase "generally and currently paid by providers" — the catchphrase of Dr. Schondelmeyer's legal opinion — is merely a quotation from the federal regulation that defines Estimated Acquisition Cost ("EAC"). (*See* Fed. Reg. Vol. 52, No. 147, July 31, 1987, at pp. 28657.) Dr. Schondelmeyer conceded at his deposition that his opinion on what Dey was required to report is based on the supposed "plain meaning" of the EAC definition — i.e., his own subjective interpretation of Medicaid regulations. (Tr. 536:22-537:19.) Further, when asked for the basis of his opinion that Medicaid's intention was to pay as close to the actual acquisition cost as feasible, Dr. Schondelmeyer referred to "statements made by the government in program memoranda, in final rules and the other documents that I've cited later down in paragraph 53." (Tr. 121:11-122:18.) Paragraph 53 lists only the obsolete 1977 HHS memo.

Dr. Schondelmeyer is not an attorney and is neither qualified nor permitted to give an opinion regarding the law. (Tr. at 200:22-201:4.) The determination of what the law means is strictly within the province of the trial court and an expert cannot opine on what he thinks the law means. *See U.S. v. Mikutowicz*, 365 F.3d 65, 73 (1st Cir. 2004). Indeed, "[e]xpert testimony proffered solely to establish the meaning of the law is presumptively improper." *Id.* (citation omitted); *Nieves-Villanueva v. Soto-Rivera*, 133 F.3d 92, 100 (1st Cir. 1997) (excluding expert testimony about the meaning of the law "because the judge's expert knowledge of the law makes any such assistance at best cumulative, and at worst prejudicial")[3]. Dr. Schondelmeyer's opinion

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[3] Although the Court in *Nieves-Villanueva* suggested in dicta that it may be difficult to draw the line between a legal opinion and a factual opinion where the expert is opining on "guidelines, handbooks, advisory rulings, interpretive bulletins, general counsel's letter opinions, [and] informational notices," *id.* at 100-101, this concern is not present here. Dr. Schondelmeyer is offering his legal interpretation of a federal regulation, 42 C.F.R. 447.301 – exactly what the rule against expert legal opinions is meant to avoid. Nor is this a complex highly-technical case, such as a patent litigation. *Id.* at n.13.

that federal regulations required manufacturers to report actual drug prices as "generally and currently" paid should, therefore, be excluded.

B. Dr. Schondelmeyer's Legal Opinion Should Also Be Excluded Because It Is Unsupported And Contradicted By The Law

Dr. Schondelmeyer's opinion on what prices manufacturers were required to report is not just outside the scope of his expertise, but is also legally incorrect. Thus, admission of such testimony is also improper because it would corrupt the proceedings with incorrect statements of the law. No regulation requires manufacturers to report prices as "generally and currently" paid. Moreover, Dr. Schondelmeyer ignores authority that contradict his legal conclusions.

In paragraphs 52 and 53 of his report, Dr. Schondelmeyer cites to 42 C.F.R. 447.301 as support for his conclusion that manufacturers must report prices "generally and currently paid." First, that regulation does not require manufacturers to report prices. The regulation is directed at CMS and State Medicaid programs which are required to "estimate" what prices are generally and currently paid and leaves open how the states may do so. Nothing in this regulation requires manufacturers to estimate or report these amounts.

Second, the regulation was enacted in 1987. Dr. Schondelmeyer cites to an HHS policy document dated December 13, 1977 – issued 10 years before the regulation existed – as support for his interpretation of the 1987 regulatory language. (Rep. at ¶ 53.) The regulations regarding EAC and how it is applied, however, were thoroughly revised in 1987. *See* 42 C.F.R. § 447.331 (1987); Fed. Reg. Vol. 52, No. 147, July 31, 1987, at pp. 28648-58. The Health Care Financing Administration's ("HCFA," now known as the Center for Medicare and Medicaid Services ("CMS")) own summary of the 1987 regulations confirm the rules were changed to account for and take advantage of declining generic prices:

> This rule *eliminates current Departmental procedures for setting limits on payments for drugs . . . and revises Medicaid rules . . . .*

> This rule enables the Federal and State governments to take advantage of savings that are currently available in the marketplace for [generic] drugs. Fed. Reg. Vol. 52, No. 147, July 31, 1987, at p. 28648 (emphasis added); *see also id*., Section IV.B., at p. 28654.

The "Departmental procedures" that were "eliminate[d]" in the 1987 regulations are the same policies from 1977 that Dr. Schondelmeyer relies upon to support his opinion as to the interpretation of the law. The 1977 regulation required that the ingredient cost portion of reimbursement be determined on a drug-by-drug basis. The 1987 revised regulations completely changed the law to allow states to set overall reimbursement "in the aggregate" across the overall reimbursement amount for all prescriptions. *See* 42 CFR 447.331(b). As the HCFA stated, "[u]nder this rule, the EAC criteria are applied as an upper limit on an aggregate basis rather than on a prescription by prescription basis." *See* Fed. Reg. Vol. 52, No. 147, Section III.I., at p. 28652. As a result, states are permitted by the federal government to make higher payments for some drugs as long as those higher payments are offset by lower payments for other drugs:

> 1. Increased State Flexibility …
>
> Under these final regulations, State agencies will be able to make higher payments for some listed drugs as long as they pay at rates lower than those listed for other drugs on the list. … Similarly, State agencies may employ essentially the same approach in meeting the limits for all other drugs. That is, the same principal of balancing payment increases for some drugs with decreases for other drugs also applies in determining whether aggregate payments exceed the limit. Fed. Reg. Vol. 52, No. 147, Section V.E.1., at p. 28655.

Furthermore, as the federal government stated in its comments to the 1987 regulations, this change in the law explicitly acknowledges that states are allowed to build a profit margin into reimbursement to encourage pharmacists to use lower priced generic drugs and assumes that there will be extensive discounting from benchmark prices:

> In the previous section, we discussed the possible effects of building into our rates for ingredients a profit margin for

> pharmacists. We expressed the hope that States would recognize the advantage of providing pharmacists with an incentive to participate in the Medicaid program and to stimulate pharmacists to engage in prudent purchasing practices and the substitution of lower cost therapeutically equivalent products. … [W]e suspect that price competition would be carried on in the form of discounts, promotional campaigns and other incentives aimed at the retail pharmacists. . . . [O]ur policy of using published prices as a basis for determining payment levels may cause wholesalers to invent new ways of offering discounts to the smaller independent retail outlets, thereby expanding the practice of discounting to those outlets and enabling them to have access to less expensive sources of pharmaceuticals. *Id.*, Section V.E.2, at p. 28656.

HCFA acknowledged, moreover, that the reported prices "overstated" actual costs. *Id.*, Section III., at p.28650. The regulation implicitly assumes that reported prices will exceed actual prices. The regulations were revised based on the assumption that manufacturers of multiple-source drugs would report "benchmark" prices and that reimbursement on such prices would result in unreported discount pricing. *See id*., Section V.E.2., at p. 28656. Accordingly, Dr. Schondelmeyer's legal opinion that the use of EAC pricing in Medicaid would alert manufacturers that states expected them to report prices that are "generally and currently paid by providers" is simply wrong — contradicted by the very regulation he cites — and inadmissible.

II. DR. SCHONDELMEYER'S OPINIONS REGARDING WHAT DEY "KNEW" OR "INTENDED" MUST BE EXCLUDED

An expert's testimony is inadmissible if, as here, it usurps the role of the jury by interpreting evidence and telling the jury what result to reach. *See U.S. v. Zajanckauskas,* 441 F.3d 32, 39 (1st Cir. 2006) ("Expert testimony does not assist where the [trier of fact] has no need for an opinion because it easily can be derived from common sense . . . or simple logic."). An expert witness is not permitted to review a contested record and proffer fact finding narratives that reflect his proposed resolution of the disputed evidence. *See In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 551 (S.D.N.Y. 2004). Conclusions regarding a party's intent,

purpose, or motivation is outside the realm of permissible expert testimony and is properly left to the trier of fact. *See Lippe v. Bairnco Corp.*, 288 B.R. 678, 687-88 (S.D.N.Y. 2003). In *In re Diet Drugs Prod. Liab. Litig.*, No. MDL 1203, 2000 WL 876900 (E.D. Pa. June 20, 2000), for example, the plaintiffs attempted to offer expert testimony that the defendant pharmaceutical company's labeling and marketing of drugs was "driven by its desire to increase profits." *Id.* at *2. The Court excluded opinion testimony on "corporate intent" because "[t]he question of intent is a classic jury question and not one for experts" and, moreover, if an expert's opinion on intent is based on documentary evidence and witness testimony then "*that* is what the jury should hear and the question of [the defendant's] intent would flow from such evidence to be determined by the jury." *Id.* at *9 (emphasis in original).

When he isn't opining on the law Dr. Schondelmeyer's report is a catalogue of what defendants (and at times, the whole industry) knew and intended:

- "The Medicaid drug program has had a consistently stated objective for its payment policy to be based on 'estimated acquisition cost' (EAC). ***Drug manufacturers were well aware of this intent*** with respect to the drug product payment under Medicaid since as far back as 1977." (Rebuttal Rep. ¶ 8.)[4]

Dr. Schondelmeyer even purports to testify on what drug manufacturers knew about what Medicaid and Medicare intended:

- "***Drug manufacturers, including Abbott, Roxane, and Dey, were aware*** that state Medicaid programs intended to use the manufacturer reported prices to commercial price databases to estimate the prices 'generally and currently paid by pharmacies' in the marketplace." (Rebuttal Rep. ¶ 13.)

- "The drug companies reported these inflated AWPs and WACs ***with the knowledge*** that such inflated prices would influence the payment for prescription drugs under Medicaid and Medicare." (Rebuttal Rep. ¶ 35.)

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[4] References to "Rebuttal Rep." are to the Rebuttal Report of Dr. Schondelmeyer, dated April 23, 2009, attached as Exhibit C to the Declaration of Neil Merkl.

Dr. Schondelmeyer also purports to read the minds of Dey executives and other witnesses after only a cursory review of the record, selected for him by counsel:

- "***Dey marketing executives knew*** how Medicare reimbursement worked, the role of increased spreads or 'margins,' and that they were selling drug products (i.e. Cromolyn Sodium Nebulizer Solution 20mg/2ml) substantially below the Medicare reimbursement rate." (Report ¶ 91.)

- "Dey set the AWP and WAC for its drug products and ***knew well*** the effect that these reported and published prices had on sales to pharmacies. ***Dey also knew well*** the effect that these reported and published prices (i.e., AWP and WAC) served in the third party reimbursement process, including the impact on Medicaid and Medicare reimbursement." (Report ¶ 93.)

- "Not only did Dey set and increase the spread amounts for its drug products, ***Dey also knew*** the impact of these spreads upon the purchase decisions of its customers." (Report ¶ 96.)

- "***The defendants routinely kept themselves informed*** of the actual reimbursement methodologies of the Medicaid and Medicare programs and ***they knew quite precisely*** what prices were being relied upon by those programs to determine their reimbursements to purchasers of defendants' drug products." (Rebuttal Rep. ¶ 36.)

- "***The critical conclusion to be drawn is that defendants knew*** that their reported AWPs … were being used by the government programs (i.e., Medicaid and Medicare) and were dictating payment amounts for tens of millions of dollars in government payments for prescriptions." (Rebuttal Rep. ¶ 37.)

Evidence of the facts, including what Dey knew or intended, is "properly presented through percipient witnesses and documentary evidence" and an expert opinion in this regard "does no more than counsel for plaintiff will do in argument, i.e., propound a particular interpretation of [the defendant's] conduct." *In re Rezulin*, 309 F. Supp. 2d at 551 (citation omitted); *see also Media Sport & Arts v. Kinney Shoe Corp.*, No. 95 CIV. 3901(PKL), 1999 WL 946354, at *3 (S.D.N.Y. Oct. 19, 1999) (excluding expert's testimony that was "not based on personal knowledge, but instead on his review of documents and depositions produced by the parties"). For example, in *Chadwick v. WellPoint, Inc.*, 561 F.3d 38 (1st Cir. 2009), the plaintiff sued for sex discrimination and sought to introduce the expert testimony of a sociologist with

expertise in employment discrimination and sex stereotyping to offer her opinion that various comments made by the defendant's employees were motivated by sex stereotyping. The court upheld the exclusion of such testimony because the trial court found that "[t]he expert, whatever her professional credentials, is not competent to testify about what *these* supervisors meant, consciously or unconsciously, in using certain words." *Id.* at 48 (emphasis in original, citation omitted). Moreover, the expert's opinion was not based on the facts of the case - in particular, she had not even read the deposition testimony of the relevant witness. *Id.* at 49 n.13. Similarly, here, Dr. Schondelmeyer is not competent to testify about what Dey intended when it made certain statements or took certain actions. Also as in *Chadwick*, Dr. Schondelmeyer has failed to review all the relevant evidence and, therefore, lacks a solid foundation for his opinions.

A. <u>Dr. Schondelmeyer concedes that he was merely weighing the evidence</u>

Dr. Schondelmeyer testified that he was asked to "evaluate the evidence" of Dey (Tr. 460:8-9) and that he "looked at documents that the company produced and reviewed them for their face value" (Tr. 461:4-5). He even admits that he was simply weighing the evidence:

> Q. So in reviewing statements and sworn testimony in preparation for your testimony today you weighed the various testimony and decided which was more credible and which was less credible? Do I have that correct?
>
> A. I would phrase it more that I identified what are the statutes, regulations, written policies of the federal and state Medicaid programs. ***And then when I read depositions or comments of various individuals I compared them, weighed them, against the official formal written policies and documents***. And when I have a difference between those I do give deference to the official formal written policies versus the comment of an individual. Yes, I do give deference to official policies.

(Tr. 199:11-200:4 (objection omitted).) Yet, Dr. Schondelmeyer was ultimately forced to concede that a jury will not need his help to understand or evaluate the evidence in this case:

> Q. So some of the documents referenced in your report a layperson could understand like a jury?
>
> A. I believe with contextual description of the marketplace ***jurors certainly could understand everything that's here***. …
>
> Q: But can you tell me, though, which of the documents you feel that's in your report that the jury would require your assistance to interpret?
>
> A: I think ***all the documents listed in my report the jury could read and probably would come to the same conclusions*** I have about them.

(Tr. 462:17-22; 464:2-8 (objections omitted).) Thus, by his own admission, Dr. Schondelmeyer has no special expertise to bring to bear in assessing Dey's knowledge or intent. The jury will be fully capable of hearing the evidence and determining what Dey knew or intended.

B. <u>Dr. Schondelmeyer's opinion is based on an inadequate review of evidence cherry-picked by counsel</u>

Worse still, Dr. Schondelmeyer's opinions on Dey's intent and knowledge are based on a woefully inadequate review of the record, cherry-picked for him by VAC's counsel. Dr. Schondelmeyer admits: "I did not attempt to and have not reviewed all documents presented in this case" and "I was provided [by counsel] a set of documents and I assumed that they had faithfully provided that information as requested." (Tr. 1686:19-21; 1689:17-20.) Dr. Schondelmeyer did not make any effort, however, to confirm that he had indeed been provided with *all* relevant evidence, including evidence that ran contrary to the conclusions of his report and the allegations of the Complaint. (*Id.* at 606:2-15; 606:19-607:14.) The documents that Dr. Schondelmeyer ultimately reviewed and considered for his report were essentially hand-selected by counsel for VAC, an interested party in this litigation. (*Id.* at 614:1-21.) For example, Dr. Schondelmeyer "can't be a hundred percent sure" that he received all the documents relating to pricing and marketing that he requested because he has "not reviewed all of the thousands upon

thousands of documents in this case." (Tr. 1691:18-21.) And, Dr. Schondelmeyer did not request or review all of Dey's marketing materials (Tr. 1685-11-14) despite opining on Dey's intent in marketing its drugs. (See, e.g., Rep. ¶ 91.)

Testimony based solely on documents and evidence cherry-picked by counsel must be excluded as biased and unreliable. *See Crowley v. Chait*, 322 F. Supp. 2d 530, 542, 547 (D.N.J. 2004) (court concerned about "the perils of [an expert] relying on evidence hand-selected…by counsel"); *Miller v. Pfizer, Inc.*, 196 F. Supp. 2d 1062, 1086 (D. Kan. 2002) (in excluding expert's testimony, the court cited concerns about "the degree of [his] reliance on pre-selected evidence from interested parties"). Dr. Schondelmeyer was not able to elaborate on the process that plaintiffs' counsel used in selecting the documents for him to review. (Tr. 599:17-600:20.)

Dr. Schondelmeyer recognized that he reviewed only a small fraction of the 3.3 million pages of documents Dey has produced during the course of this action. He admitted during his deposition that it would be "fair" to say that he did not look at the full Dey production in this case and that he did not ask for, want or expect to read the full Dey production. (Tr. 588:5-11; 590:4-9; 600:2-12.) He did not even request access to the full Dey database so that he could select relevant documents on his own, although he could have. (*Id.* at 590:16-22.) In fact, Dr. Schondelmeyer cites to *less than twenty-five* Dey documents out of the 3.3 million pages of documents that Dey has produced. (Rep. ¶¶ 20, 90-99.) Thus, his report is not the result of an objective and adequate investigation into the relevant facts of this case and should be excluded.

The lack of a thorough review of the record renders Dr. Schondelmeyer's opinions of Dey's knowledge and intent baseless and inadmissible. For example, as to whether Dey knew about the prices charged by wholesalers to retailers, Dr. Schondelmeyer admits that his opinion of Dey's knowledge is based on pure speculation – he did not rely on any scholarly research or

review of document, but would simply "be extremely surprised if it wasn't true." (Tr. 521:13-522:18.) Similarly, on the central issue Dey's price reporting, Dr. Schondelmeyer admits that he did not review all of Dey's price reporting from 1992 through 2005 despite purporting to give opinions on why Dey reported the prices it did: "I did not feel it was necessary to review each and every price reported by Dey and the detailed actual prices by Dey." (Tr. 780:14-21.) Moreover, although Dr. Schondelmeyer expounds on the supposed knowledge and beliefs held by Dey, he does not cite to any deposition testimony of actual Dey personnel because he thinks "the documents themselves in the way they were quoted in my report were sufficient to make the opinions that I've arrived at." (Tr. 603:1-12.) Nor, in his deposition, could Dr. Schondelmeyer recall any deposition testimony which supported his opinion about Dey's knowledge. (*Id.* at 578:13-17; 581:2-7; 582:16-20.) In fact, he could not even recall how many Dey deposition transcripts he read while preparing the Report and admitted that he did not read all of the depositions taken in the case. (*Id.* at 582:8-10; 600:21-601:10.) For the transcripts that he did actually review, Dr. Schondelmeyer testified that he "did kind of a skim read and looked for issues with respect to reimbursement." (*Id.* at 825:5-6.) Numerous courts have excluded or limited expert testimony because such a methodology is unreliable. *See, e.g.*, *Chadwick*, 561 F.3d at 49; *see also Roussell v. Brinker Int'l, Inc.*, No. H-05-3733, 2008 U.S. Dist. LEXIS 52568, at *102, 105 (S.D. Tex. July 9, 2008) (finding that expert's conclusions are less reliable when based on materials and individuals selected by counsel for review, expert did not know how the selections were made, and the small sample of data reviewed weighed against admissibility); *McGovern v. Brigham & Women's Hosp.*, 584 F. Supp. 2d 418, 424, 426 (D. Mass. 2008) (excluding testimony that was based on research conducted only for litigation and testifying); *Lippe*, 288 B.R. at 690-91, 697 (excluding testimony because, among other things,

expert was unable to explain bases for opinion and relied on what counsel told her rather than conducting independent investigation).

Put simply, Dr. Schondelmeyer proposes to testify to the jury about Dey's knowledge and intent in the guise of an expert when, in fact, he is doing nothing more than offering his own spin on the evidence. Dr. Schondelmeyer is actually less fit than a jury to interpret the facts of this case because by his own admission he didn't review all of the facts; rather he reviewed only a subset of the facts carefully selected for him by Plaintiff's counsel. Further, expert testimony is inherently powerful and presents the likely risk that jurors will accord undue weight to unsupported expert statements. *See U.S. v. Fosher*, 590 F.2d 381, 383 (1st Cir. 1979) (noting that expert testimony may "create a substantial danger of undue prejudice and confusion because of its aura of special reliability and trustworthiness"). For these reasons, Dr. Schondelmeyer's opinions on Dey's knowledge and intent should be excluded.

III. DR. SCHONDELMEYER'S OPINIONS REGARDING THE KNOWLEDGE AND INTENT OF MEDICAID AND MEDICARE SHOULD BE EXCLUDED

A. Testimony About The Intent and Knowledge of Medicaid or Medicare is Inadmissible

Dr. Schondelmeyer also offers a series of opinions regarding what Medicaid and Medicare officials knew and did which are simply based, again, on his weighing of the evidence and making credibility determinations – including on the most contested factual issues in this case:

- "Policymakers and both Medicaid and Medicare program administrators ***were unaware*** of the conduct of certain drug manufacturers whereby reported prices (i.e. AWP, WAC, DP, and list prices) were inflated well beyond the actual prices in order to engineer an inflated price spread and to result in inflated reimbursement, including Medicaid and Medicare reimbursement." (Rep. ¶ 22.)

- "***Medicaid and Medicare currently and historically have relied*** upon manufacturers' reporting of prices that do reflect the 'prices generally and currently paid by providers' in the marketplace." (Rep. ¶ 80.)

- "State Medicaid programs are usually sparsely staffed with the employee(s) having a responsibility for a wide range of issues, initiatives and systems …. This sparse staff … does not have time to review all drug product prices on a routine basis …." (Rep. ¶ 110.)

- "***The state Medicaid programs expected*** that the manufacturer prices reported to the price databases were based on actual or transaction prices, or based on the known relationship to actual prices." (Rep. ¶ 162.)

- "***The intent of the Medicaid program*** regarding drug product reimbursement is 'to have each state's estimated acquisition cost as close as feasible to the price generally and currently paid by the provider.'" (Rebuttal Rep. ¶ 8.)

Dr. Schondelmeyer also purports to opine on the intent and knowledge of all 50 state Medicaid programs, testifying that "states intended to follow the federal directives so that they could qualify for the federal cost sharing." (Tr. 138:11-139:6; *see also* Rep. ¶¶ 53, 55, 78, 79, 80, 149, 152, 153.) Dr. Schondelmeyer even draws conclusions about what individual state officials "understood" based on his alleged review of the factual evidence:

- "There is extensive evidence indicating that ***state officials understood***, and attempted to implement, estimated acquisition cost (EAC) as the 'price generally and currently paid by providers' in a manner that was consistent with federal policy." (Rebuttal Rep. ¶ 21.)

Dr. Schondelmeyer, however, did not speak with anyone from the Medicaid or Medicare programs regarding this action, has not reviewed documents from all state Medicaid programs, and has not reviewed all depositions of current or former Medicaid or Medicare officials. For example, Dr. Schondelmeyer testified that speaking to Medicaid officials who were in place at various times would be a good way to discern the intent of Medicaid, but that he did not do so. (Tr. 1257:2-11.) Nor did Dr. Schondelmeyer review all of the deposition transcripts of Medicaid officials which were available to him in this case. (Tr. 1257:12-1258:14.) As with his testimony about Dey's practices, Dr. Schondelmeyer's testimony about the knowledge and intent of Medicare and Medicaid is simply his interpretation of various documents. However, Dr.

Schondelmeyer could not identify more than three state Medicaid directors who had expressed to him their expectations of the Medicaid program. (Tr. 758:13-765:9.)

Moreover, Dr. Schondelmeyer testified that he would essentially ignore the testimony of state Medicaid officials who gave testimony on a specific state's intention if it was in conflict with his own view of the state's intention. For example, Dr. Schondelmeyer testified that state Medicaid programs intended to pay as close as feasible to actual acquisition cost. However, the Medicaid pharmacy administrator in Minnesota testified that the intent of that program was to pay $8 to $10 more than actual acquisition cost. Dr. Schondelmeyer ignored that testimony because he "gives more weight" to official documents and the official statutes, rules, regulations and policies "than the comment of an individual" – even when the individual is the 30(b)(6) witness for a state's Medicaid program. (Tr. 189:17-199:10.) Yet, when deposition testimony supports his own opinion of state Medicaid programs' intent, Dr. Schondelmeyer freely cites to the depositions of numerous state Medicaid pharmacy administrators and 30(b)(6) witnesses. (Rep. ¶¶ 64, 79, 80, 137, 138, 145, 153, 154, 156.) Dr. Schondelmeyer's selective review of state Medicaid administrator deposition transcripts undermines the reliability of and underscores the lack of foundation for his opinions on the intent and knowledge of Medicaid and Medicare. *See Crowley*, 322 F. Supp. 2d at 542.

B. Testimony that "inflated prices" caused Medicaid and Medicare to overpay providers is speculative

Dr. Schondelmeyer also opines that Medicaid and Medicare would have paid less for prescription drugs if different information regarding Dey's pricing were available. (Report ¶ 101, 212.) This opinion is without basis and should be excluded. Dr. Schondelmeyer is not an economist and lacks expertise to offer an opinion on how reimbursements would have changed had manufacturers reported different prices. Dr. Schondelmeyer's conclusion that Medicaid and

Medicare would have paid less for prescription drugs if not for Dey's actions amounts to, in his own words, conclusions regarding what "might have" happened if manufacturers had reported "accurate" prices. (Tr. 159:16-160:7.) With regard to Medicare in particular, Dr. Schondelmeyer's opinions are pure speculation. With no factual support and no expert analysis whatsoever, Dr. Schondelmeyer opines that an inflated AWP for one or more NDCs *may* cause an inflated median AWP which, in turn, *may* result in higher reimbursements; conversely, a "truthful" AWP *may* result in a lower reimbursement. (Rep. ¶¶ 182, 183).

All of Dr. Schondelmeyer's opinions regarding whether Dey reported "inflated" prices should be excluded because they are based upon his review of documents exclusively selected by Plaintiff's counsel and taken out of the context of the full factual record. *See Crowley*, 322 F. Supp. 2d at 542 (excluding expert testimony where the expert did not conduct "independent analyses" but merely relied on information supplied by counsel); *Willis v. Besam Automated Entrance Sys., Inc.*, No. 04-CV-0913, 2005 U.S. Dist. LEXIS 26466, at *16-17 (E.D. Pa. Nov. 3, 2005) (excluding testimony because "[i]nstead of conducting his own independent investigation, [the expert] merely relie[d] on documents provided to him by … counsel"). Indeed, Dr. Schondelmeyer admits that he did not review all of Dey's pricing information from 1992 to 2005 despite purporting to offer an opinion on whether the prices were "inflated." (Tr. 780:5-21.)

Dr. Schondelmeyer also did not conduct Dey-specific analyses. For example, Dr. Schondelmeyer did not perform an analysis about the effect of impact of Dey's pricing practices (specifically, Dey's practice of decreasing its WAC over time) on overall market expenditures, although this analysis would clearly be relevant to his overall conclusion. (Tr. at 499:5-501:16; 569:21-570:22.) Although Dr. Schondelmeyer states in his report that Dey set "high" WACs (Rep. ¶ 90), Dr. Schondelmeyer was not able to affirmatively state during his deposition whether

or not Dey WACs were inflated or whether they went up or down over the course of the relevant time period. (Tr. 618:16-624:20; 631:21-634:15.) An expert is required to perform independent analyses on the information upon which he relies. *See Crowley*, 322 F. Supp. 2d at 542.

As to whether Dey's price reporting caused Medicaid or Medicare to pay higher reimbursements, Dr. Schondelmeyer fails to mention or consider a multitude of factors that may have affected Medicaid and Medicare reimbursement. Instead, he merely summarily concluded if Dey reported its prices differently, Medicaid and Medicare would have paid less for drugs. Yet, Dr. Schondelmeyer testified at length regarding various factors – not mentioned in his report – that may affect Medicaid or Medicare's decision to keep reimbursements high:

- Access to Care: In a recent report that Dr. Schondelmeyer penned regarding reimbursement in the State of California, Dr. Schondelmeyer concluded that a reimbursement cut "would in some cases result in paying the pharmacy below their actual costs for the drug product and in some cases below their actual cost of dispensing for the drug product and that such behavior could or such payment policy could result in pharmacies either refusing to provide prescription drugs under the Medi-Cal program, certain prescription drugs, or to participate in general, and changes in that could affect access of patients in California to outpatient drugs." (*Id.* at 72:16-73:4) Dr. Schondelmeyer later testified that the state may consider whether there's an impact on access to care when setting reimbursement rates. (*Id.* at 410:2-10.)

- Dispensing Fees: In another report, Dr. Schondelmeyer specifically took into account the dispensing fee as it related to overall reimbursement. (Tr. 293:1-296:14.) However, for the Dey Report, Dr. Schondelmeyer did not consider the effect that lowering reimbursement would have on the dispensing fee. (*Id.* at 165:10-15.)

- Profit: Dr. Schondelmeyer also acknowledges that states consider profit for the pharmacies when setting dispensing fees and in fact that Medicaid policy supports that consideration. (*See id.* at 487:8-489:19; 490:8-11; 597:13-19; 927:21-928:4; 1062:4-11.)

- Inflation and Other Costs: Dr. Schondelmeyer also testified as to the importance of keeping in mind such factors as inflation and other factors that contribute to provider costs changing over time. (*Id.* at 336:3-14.) In a report written for CMS, he specifically stated that "The payment amount for drug products to pharmacies and other providers under Medicaid and Medicare cannot be viewed in isolation from the other payments to such providers for storage, handling, counseling, dispensing, billing, record keeping and administration." (*Id.* at 525:6-16; Abbott Ex. 381, at 6.) In fact, Dr. Schondelmeyer wrote that a margin relative to acquisition cost "may be appropriate" given these other costs. (Tr. 529:9-530:22; Abbott Ex. 381, at 6.)

Dr. Schondelmeyer recognizes that "if pharmacies are paid below their cost for product and dispensing in aggregate over time in a program, they may choose not to participate in that program." (Tr. 333:4-7.) Moreover, both product cost and dispensing fee reimbursement "will influence the business decision a pharmacy makes as to whether or not to accept or participate in a third party program." (Tr. 338:4-6.) These considerations were not analyzed in Dr. Schondelmeyer's report.

Dr. Schondelmeyer also cites to no support for his contention that "increases in manufacturer reported prices and increases in utilization ***appear*** to have been the major contributors to growth in drug expenditures for the Medicare Part B program." (Rep. ¶ 178.) Nor did Dr. Schondelmeyer perform any expert or scholarly analysis to discern the actual causes of the growth in Medicare payments or figure out which causes had what level of influence; instead he relies solely on what "appears" to be true with no citation to any evidence.

CONCLUSION

For the foregoing reasons, Dey respectfully requests that the Court enter an Order granting Dey's motion to exclude the reports and testimony of Dr. Stephen W. Schondelmeyer, and grant Dey such other, further, and different relief as the Court deems to be just and proper.

Dated: March 24, 2010

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on March 24, 2010, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Neil Merkl
Neil Merkl